DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

August 3, 2016

Jonas Kuehne, M.D.
Medical Director and Co-Founder
Cryohealthcare, Inc.
351 N. La Cienega Boulevard
Los Angeles, California 90048

Document Number: CPT1401012

Dear Dr. Kuehne:

It has come to our attention that your firm is currently marketing the Cryosauna, Cryochamber, Local Cryo-Stimulation Device, and Electric Local Cryo-Stimulation Device, which include walk-in chambers and applicators and are indicated for use in "cryotherapy." The Cryosauna, Cryochamber, Local Cryo-Stimulation, and Electric Local Cryo-Stimulation Devices appear to meet the definition of a device as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

We have conducted a review of our files and have been unable to identify any Food and Drug Administration (FDA) clearance or approval number for the Cryosauna, Cryochamber, Local Cryo-Stimulation, and Electric Local Cryo-Stimulation Devices. A review of your firm's website, www.cryohealthcare.com, reveals that these devices are being promoted and marketed for treating medical conditions and provide therapy for the following:

1. Injuries (non-specific) and injury recovery
2. Tissue repair
3. Rheumatoid arthritis
4. Inflammation reduction
5. Post-surgical recovery
6. Insomnia
7. Rheumatism
8. Muscle and joint pain
9. Various skin conditions
10. Mood enhancement for depressive and anxiety disorders
11. Fibromyalgia
12. Improvement of motor skills
13. Multiple sclerosis
14. Psoriatic arthritis
15. Alzheimer's disease
16. Spinal decompression and spine diseases

17. Cervical disc herniation

The FDA is not aware of any evidence to substantiate such claims. These claims may be considered false and misleading, causing the Cryosauna, Cryochamber, Local Cryo-Stimulation Device, and Electric Local Cryo-Stimulation Device to be misbranded under the Act (see section 502(q) of the Act).

In addition, these devices expose users to liquid nitrogen (cryogenic gas) at temperatures ranging from -200 to -240^{o}F. The devices cool the skin for a period of 1.5 - 3 minutes. During the 1.5 - 3 minute session, your firm claims that the user's average skin temperature drops to 10°C (50°F) while the coldest skin temperature can be 0°C (32°F). Your firm also states that "core body temperature remains unchanged throughout the process, however, it may drop slightly afterwards." These devices are intended to be used for duration of 5 - 10 times in close succession (separated by 1 - 2 days, e.g. 3x/week) and 1 or 2 times per week thereafter.

Please be advised that water circulating cold pack devices are Class II 510(k) exempt under product code ILO. These devices are generally indicated for applying cooling to the skin. However, the four devices manufactured by Cryohealthcare, Inc. mentioned above, include expanded indications including the 17 medical claims as noted above. These four devices also use Nitrogen whereas the class of devices under 21 CFR 890.5720 generally uses water to achieve cooling. The differences in indications for use and technological characteristics exceed the limitation under 21 CFR 890.9(a) as a device "intended for a use different from the intended use of a legally marketed device in that generic type of device" and as a device that "operates using a different fundamental scientific technology than a legally marketed device in that generic type of device." Therefore, these four devices would require a premarket submission to provide performance testing, which supports the claims beyond the cleared indications for use for water circulating cold pack devices.

If you do not believe that you are required to obtain FDA clearance for the Cryosauna, Cryochamber, Local Cryo-Stimulation, and Electric Local Cryo-Stimulation Devices based on the above-mentioned medical claims, intended use, and technology, please provide us with the basis for that determination.

We have assigned a unique document number that is cited above. Any further correspondence regarding this letter should reference this document number and should be submitted within 30 days to:

Complaints Program Manager, WO66-3684
Division of Analysis and Program Operations
Office of Compliance
Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993

If you have questions relating to this matter, please feel free to call Ms. Xuan Vo at 301-796-5770, or log onto our website at www.fda.gov for general information relating to FDA device requirements.

Sincerely yours,

/s/

Shanika L. Booth
Chief
Surveillance and Enforcement Branch II
Division of Premarket and
Labeling Compliance
Office of Compliance
Center for Devices and
Radiological Health